

REMARKS

This responds to the non-final Office Action dated 5 October 2007. Claims 1, 33, and 38-60 have been amended. Support for these amendments can be found variously throughout the specification; including, for example, original claims 1, 21, 33, 38-60, page 4, line 21 to page 5, line 6, and FIG. 4. No new matter has been added. Accordingly, claims 1-62 are presently pending in the application, each of which Applicants believe is in condition for allowance. Applicants respectfully request reexamination and reconsideration in light of the above amendments and the following remarks.

For simplicity and clarity purposes in responding to the Office Action, Applicants' remarks are primarily focused on the rejections applied to the independent claims (*i.e.*, claims 1, 21, 33, 38, 43, 50, 55, and 60) as outlined in the Office Action with the understanding that the dependent claims are patentable for at least the same reasons (and in most cases other reasons) that the independent claims are patentable. Applicant expressly reserves the right to argue the patentability of the dependent claims separately in any future proceedings.

Claim Rejections – 35 U.S.C. § 102

In the Action, the Examiner rejected claims 1, 3-5, 8, 19, 20, 38, 40, 42-52, 54-56, and 59 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,293,961 to Schwartz et al. ("Schwartz"). The Examiner also rejected claims 1, 2, 10-17, 19, 20, 38-41, 43-48, 50-52, and 55 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,702,397 to Goble et al. ("Goble"). Applicants respectfully traverse this rejection.

Independent claims 1, 38, 43, 50, and 55, as amended, recite, *inter alia*, a “vascular closure assembly, comprising: an anchor; a collagen; a suture coupled to the anchor and extending through the collagen.”

In contrast, Schwartz clearly fails to disclose, teach, or suggest each and every limitation recited in independent claims 1, 38, 43, 50, and 55. For example, at the very least, Schwartz fails to disclose, teach, or suggest a “vascular closure assembly” comprising “a collagen” and “a suture coupled to [an] anchor and extending through the collagen.” Rather, Schwartz merely discloses a suture 40 used to pull two sides of a soft tissue defect together, or to attach soft tissue to bone, using a first anchor 20 and a second anchor 80 connected to suture 40. Col. 3, lines 38-50.

Goble also fails to disclose, teach, or suggest each and every limitation recited in independent claims 1, 38, 43, 50, and 55. For example, at the very least, Goble also fails to disclose, teach, or suggest a “vascular closure assembly” comprising “a collagen” and “a suture coupled to [an] anchor and extending through the collagen.” Instead, Goble merely discloses a bone anchor 80 that is anchored to bone; the bone anchor 80 secures a ligament graft to the bone by engaging sutures 27 attached to the ligament. Col. 7, lines 4-15 and col. 7, line 62 to col. 8, line 4.

Accordingly, because Schwartz and Goble each fails to disclose, teach, or suggest every element of independent claims 1, 38, 43, 50, and 55, a *prima facie* anticipation rejection has not been established. See, e.g., *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art

reference”); *see also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1566 (Fed. Cir. 1989) (“The identical invention must be shown in as complete detail as is contained in the . . . claim.”).

Moreover, aside from the novel limitations recited therein, claims 2-5, 8, 10-17, 19, 20, 39-42, 44-49, 51, 52, 54-56, and 59 are also allowable at least by virtue of their dependency upon allowable base claims 1, 38, 43, 50, and 55. Applicants respectfully request, therefore, that the rejection of claims 2-5, 8, 10-17, 19, 20, 39-42, 44-49, 51, 52, 54-56, and 59 under 35 U.S.C. § 102(b) be withdrawn, and these claims be allowed.

Claim Rejections – 35 U.S.C. § 103

In the Action, the Examiner rejected claims 7 and 60-62 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Schwartz in view of the present Specification. The Examiner also rejected claims 3-5, 8, 42, 49, 54, 59, and 60-62 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Goble in view of Schwartz and the present Specification. The Examiner additionally rejected claims 1-5, 7, 8, 10-17, 19-52, and 54-62 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,549,633 to Evans et al. (“Evans”) in view of Schwartz and Goble. Applicants respectfully traverse this rejection.

Claims 3-5, 7, 8, 42, 49, 54, 59, and 60-62 each depend from independent claims 1, 38, 43, 50, and 55. By virtue of this dependency, Applicants submit that claims 3-5, 7, 8, 42, 49, 54, 59, and 60-62 are allowable over Schwartz and Goble for at least the same reasons given above with respect to claim 1, 38, 43, 50, and 55. In addition, Applicant submits that claims 3-5, 7, 8,

42, 49, 54, 59, and 60-62 are further distinguished over the cited references by the additional elements recited therein, and particularly with respect to each claimed combination.

As conceded in the Office Action, Evans fails to disclose, teach, or even suggest the use of “a suture locking mechanism” as recited in claim 1, “a locking device” as recited in claims 21 and 55, “a means for locking [a] suture” as recited in claim 33, “a plurality of locking posts residing in [a] housing” as recited in claim 38, “a channel formed in [a] housing defining a suture pathway” as recited in claim 43, “an inner housing assembly” that resides in an “internal space formed by an external housing” as recited in claim 50, or “a housing having a base and at least one flexible sidewall” as recited in claim 60.

Additionally, Applicants respectfully submit that the Examiner’s rationale for combining the locking devices of Schwartz et al. or Goble et al. with a tissue puncture closure device as disclosed by Evans is insufficient to establish a *prima facie* case of obviousness. On page 4 of the Office Action, the Examiner asserts that “[i]t would have been obvious to have used any of the various suture locking devices disclosed by Schwartz and Goble instead of that disclosed by Evans, as merely an obvious alternative suture locking device capable of performing the same task in the same manner as Evans’s.” However, neither Nash nor Goble discloses a vascular closure apparatus comprising a device for locking a suture. Rather, Nash discloses a device for anchoring ligament to bone and Goble discloses a device for securing a suture to pull together soft tissue on opposite sides of a tissue defect or to anchor soft tissue to bone.

Additionally, neither Nash nor Goble discloses a holding means that functions in analogous manner to the holding means disclosed by Evans. Instead, Evans clearly teaches that that no force, or very little force, is required to maintain a collagen foam mass 22 in place at a

puncture tract 10A. Evans states that “frictional engagement between the inner surface of the passageway 40 of the mass 22 and the exterior surface of the extending portions 24A and 24B of the suture 24 should be sufficient to hold the mass 22 in place in the puncture tract 10A.” Col. 8, lines 15-22. Evans further teaches that a holding means may be employed if deemed necessary to hold the mass 22 in place. The additional holding means may comprise a “second knot 24E” tied in suture 24, or a “washer or disk 24” that has a “central opening [] sized so that its interior surface frictionally engages the suture portions extending therethrough.” Col. 8, lines 41-46. Essentially, disk 24 does not lock suture 24 in place, but rather, the disk 24 merely has sufficient frictional contact with suture 24 that it can remain in place when minimal force is applied (e.g., force exerted by mass 22).

In contrast to Evans, Goble discloses a bone anchor 80 for anchoring ligament to bone by applying tension to sutures 27, thereby locking sutures 27 in place under the tension. Col. 7, line 62 to col. 8, line 4. The device disclosed by Goble is not used to hold a small mass in place at a puncture site under low tension, as disclosed by Evans. Rather, Goble teaches that bone anchor 80 comprises a spherical ball 87 or cylinder 107 that locks sutures 27 in place when a tensile force is applied to the sutures 27. Col. 8, lines 4-15. Spherical ball 87 or cylinder 107 forces sutures 27 against a conical section 86 of bone anchor 80, locking sutures 27 in place under the tensile force exerted by sutures 27 on bone anchor 80. Col. 8, lines 4-10. There is no reason why one of skill in the art would combine the bone anchor of Goble, which uses tension to lock sutures in place, with the holding means of Evans, which is merely used to help hold a collagen foam mass in place at a puncture site.

Similarly, in contrast to Evans, Schwartz discloses a suture locking device having two anchors positioned on opposite sides of a defect. Col. 3, lines 38-46. The suture locking device disclosed by Schwartz may also be used to fasten soft tissue to bone, with one anchor positioned in the bone and the other anchor positioned in the soft tissue. Col. 3, lines 47-50. In either case, tension is applied to a suture 40 and anchor 20, which is capable of locking suture 40 in place. As stated in Schwartz, a small amount of tension applied to suture 40 acts to pull anchor 20 toward a second anchor 80, which is also connected to suture 40. Col. 4, lines 13-18. When anchor 20 is seated, additional tension applied to suture 40 locks suture 40 into place in anchor 20. Col. 4, lines 19-21; *see also*, col. 6, lines 1-3 (“With tension on suture 40, wedge 50 may be pushed into cannula 22. Suture 40 then becomes locked between arch 54 and the inner wall of cannula 22.”). There is no reason why one of skill in the art would combine the bone suture locking device of Evans, which uses tension between the locking anchor and the suture to lock the suture in place, with the holding means of Evans, which is merely used to help hold a collagen foam mass in place at a puncture site.

Further, Evans teaches away from using a suture locking device as disclosed by either Schwartz or Goble. Evans teaches that a holding means for holding mass 22 in place may comprise a knot 24E or a washer or disk 46. Col. 8, lines 30-44 and FIGS. 13-18. Each of the holding means shown and described in Evans has a relatively low profile relative to the puncture site; a knot in a suture is a relatively small feature and a washer or disk has a relatively flat profile. In contrast, the suture locking devices disclosed in Schwartz and Goble differ from the holding means taught by Evans in that they are relatively bulky in size and shape, and have protruding profiles in contrast to the low profile of the holding means disclosed by Evans.

Accordingly, for each the above reasons, applicant respectfully requests that the rejection of independent claims 1, 21, 33, 38, 43, 50, 55, and 60 under 35 U.S.C. § 103 be withdrawn, and these claims be allowed. Moreover, aside from the novel limitations recited therein, claims 2-5, 7, 8, 10-17, 19, 20, 22-32, 34-42, 44-49, 51, 52, 54, 59, and 60-62 are also allowable at least by virtue of their dependency upon allowable base claims 1, 21, 33, 38, 43, 50, 55, and 60. Applicants respectfully request, therefore, that the rejection of claims 2-5, 7, 8, 10-17, 19, 20, 22-32, 34-42, 44-49, 51, 52, 54, 59, and 60-62 under 35 U.S.C. § 102(b) be withdrawn, and these claims be allowed.

Conclusion

For at least the foregoing reasons, Applicants believe that each of the presently pending claims in this application is in immediate condition for allowance. Accordingly, Applicants respectfully request a favorable action on the merits. If the Examiner has any further comments or suggestions, Applicants invite the Examiner to telephone the undersigned attorney to expedite the handling of this matter.

Dated: _____

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Respectfully submitted,



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